MAR 2 8 2006

K051197

510(k) SUMMARY

submitters Information: Inno-Health Technology, Inc.
8F-2, No.61, Kung Yi Road Sec. 2,
Taichung, Taiwan 408, Republic of China

Contact Person: Terry C. Chiang
Tel: +886- 4 2327 0788

Date Summary Prepared: March 30, 2005

Device Information:

Classification name:	Electro-Acupuncture.
Common / Usual name:	ACULIFE/Model SMW-01.
Classification:	Class II.
Regulatory Class:	Unclassified.
Product Code:	BWK.

Substantial equivalence: S.H.P International / model ACUSTIM (510k number: k014237)

Description of the Device:

The device consists of a battery powered portable instrument, with a basic power pack which is connected by conducting lead wire to two electrodes (one probe electrode and one big adhesive electrode) which make contact for hands stimulation.

Indications For Use:

The intended use of ACULIFE/Model SMW-01 is an ELECTRO-ACUPUNCTURE DEVICE for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

ACULIFE/model SMW-01 is intended for the stimulation at hands of patient.

Technological Characteristics:

ACULIFE uses a 9V/DC battery or 9V adaptor as the supply power of the stimulation unit. It can be adjusted for the output amplitude, keep the memory of chosen amplitude, and set the operation time. The electrode combination and lead wire provide the electro-acupuncture stimulation for hand by or on the order of a qualified practitioner of acupuncture as determined by the states.

Performance Data:

- EN 60601-1 & EN 60601-1-1 for Electric Safety.
- EN 60601-1-2 for EMC.
- ISO 10993 for biocompatibility.
- Skin impedance test for the estimation of loading.
- Output Characteristics testing for product specification.

Statement of indication for use : See the following page.

Conclusion : Based on the documents provided in the 510(K) submission, the Inno-Health electrode acupuncture, model ACULIFE/ SMW-01 is substantial equivalent the chosen FDA cleared model : S.H.P International / model ACUSTIM.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2006

Mr. Terry Chiang
President
Inno-Health Technology, Inc.
8F-2, No. 61, Kung Yi Road
Section 2
Taichung, Taiwan 408
Republic of China

Re: K051197
Trade/Device Name: ACULIFE Model SMW-01
Regulation Name: Electro-Acupuncture Stimulator
Regulatory Class: Unclassified
Product Code: BWK
Dated: January 12, 2006
Received: January 24, 2006

Dear Mr. Chiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for use

510(k) Number (if known): K051197

Device Name: Electro-Acupuncture; ACULIFE/Model SMW-01.

Indications For Use:

The intended use of ACULIFE/Model SMW-01 is an ELECTRO-ACUPUNCTURE DEVICE for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

ACULIFE/model SMW-01 is intended for the stimulation at hands of patient.

Prescription Use √ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051197